UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

REGENLAB USA LLC, Plaintiff, v. ESTAR TECHNOLOGIES LTD., ECLIPSE AESTHETICS LLC, HEALEON MEDICAL, INC., Defendants.	)	Civil Action No. 16-cv-08771 (ALC)

OPPOSITION TO DEFENDANTS' MOTION
FOR PRELIMINARY INJUNCTION AND STAY

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Pursuant to the Court's June 29, 2017 Order, (Dkt. 87), Plaintiff RegenLab USA LLC ("RegenLab" or "Plaintiff") submits this Opposition to Defendants Eclipse Aesthetics LLC ("Eclipse") and Healeon Medical, Inc.'s ("Healeon") (collectively, "Defendants") Motion for Preliminary Injunction and Stay, (Dkt. 90).

I. INTRODUCTION

A determination of whether to stay or enjoin a case invokes questions of law, policy, and procedure. Defendants' Motion fails on all levels. At the outset, Defendants admit that their purported basis to sever and stay—the "customer suit exception"—is inapplicable here. (Dkt. 90 at 22 ("While the direct application of the customer suit exception cannot be utilized…")). Indeed, Defendants fail to cite *any* authority that is remotely on point with the facts and posture of this case. Nevertheless, Defendants argue that the rationale of the customer suit exception makes sever and stay proper. Defendants are wrong. The concerns sought to be prevented by the exception—forum shopping, duplicative litigation and risk of inconsistent judgments—are not present in this case because Estar and Defendants have been sued in the same district. Perhaps most important, litigation with Estar alone will not resolve major issues concerning Defendants' separate and independent acts of infringement. In any event, Defendants' request to sever and stay is procedurally improper at least because Defendants and Estar have motions to dismiss currently pending with the Court.

In addition, Defendants have failed to meet their high burden to enjoin RegenLab from prosecuting other lawsuits or communicating information about its lawsuits to the public. RegenLab has an absolute right to assert its patent rights and report the facts of its well-pleaded allegations. Moreover, Defendants have not identified any specific harm suffered as a result of RegenLab's lawsuits or communications to warrant an injunction. Neither have Defendants

shown a likelihood of success on the merits. Accordingly, Defendants' entire Motion should be denied.[1]

II. THE COURT SHOULD DENY DEFENDANTS' MOTION TO SEVER AND STAY BECAUSE THE CUSTOMER SUIT EXCEPTION AND ITS "RATIONALE" ARE INAPPLICABLE

A. Defendants agree that the customer suit exception does not apply here

Defendants agree that their purported basis to sever and stay—the "customer suit exception"—does not apply in this case. (Dkt. 90 at 22.) The "customer suit exception" is an exception to the general rule that a first-filed action takes precedence over a second-filed action relating to the same issues. *Tegic Commc'ns Corp. v. Bd. Of Regents of Univ. of Tex. Sys.*, 458 F.3d 1335, 1343 (Fed. Cir. 2006). In patent litigation, the customer suit exception may apply if a patent owner first files a lawsuit against a customer of a manufacturer and then a second, subsequent lawsuit commences with the manufacturer *in another* district. *Tegic*, 458 F.3d at 1343. Here, there is no preference for litigating a second, subsequent litigation because RegenLab filed its first case against Estar (the manufacturer) *and* Defendants.

B. The rationale for the customer suit exception is not applicable because Estar and Defendants have been sued in the same district

Defendants nevertheless argue that the rationale of the customer suit exception makes sever and stay proper. (Dkt. 90 at 22.) The purpose of the customer suit exception is to avoid forum shopping, duplicative litigation and inconsistent conclusions in *different* districts. *Spread Spectrum Screening LLC v. Eastman Kodak Co.*, 657 F.3d 1349, 1358 (Fed. Cir. 2011) ("Because [the manufacturer did not file a separate declaratory judgment action against the patentee], we are not presented with a traditional first-to-file scenario, and the underlying policy

[1] As appreciated by the Court at the June 29 pre-motion conference, oral argument may not be needed to resolve these issues, and are "fruitless at this point" given the current posture of the case. RegenLab believes that Defendants' Motion can and should be denied on the papers.

considerations associated with a 'race to the courthouse,' such as deterring forum shopping, are not implicated."); *In re Dell, Inc.*, 600 Fed.Appx. 728, 730 (Fed. Cir. 2015) (unpublished) ("Petitioners cite a number of cases dealing with the customer-suit exception . . . [b]ut they cite no appellate court case, and we are aware of none, that sets forth the proposition that a district court must stay proceedings against a customer in the same litigation that will, regardless of the requested stay, go forward against the supplier."); *see also Carucel Investments, L.P. v. Novatel Wireless, Inc.*, No. 16-cv-118-H-KSC, 2016 WL 8738221, at *2 (S.D. Cal. May 13, 2016) (citing *In re Dell*). Here, Estar and Defendants have been sued in the same district and there are no such concerns. As a result, the rationale cannot be applied in this case.

District courts across the country have held that when a patentee sues a manufacturer and its customer in the same district the interests behind the rationale are not served by the application of the customer suit exception. *See, e.g., Rates Tech., Inc. v. New York Telephone Co.*, No. 94 Civ. 9297 (DC), 1995 WL 438954, at *2-3 (S.D.N.Y. July 25, 1995) ("The customer suit exception is inapplicable to the instant action. First, there is no question of competing lawsuits and no issue of priority between actions. The parties have not cited to any related proceedings, and all the alleged infringers are parties to this action."); *Heinz Kettler GMBH & Co. v. Indian Indus., Inc.*, 575 F. Supp. 2d 728, 730 (E.D. Va. 2008) ("[T]his case does not present a situation where two suits are pending in different jurisdictions, nor a danger of inconsistent conclusions about the infringement of plaintiffs' patent."); *Carucel Investments, L.P. v. Novatel Wireless, Inc.*, No. 16-cv-118-H-KSC, 2016 WL 8738221 (S.D. Cal. May 13, 2016); *Edizone, LLC v. Schering-Plough Healthcare Prod., Inc.*, No. 2:10-CV-855 TS, 2011 WL 1559944, at *2 (D. Utah Apr. 25, 2011) (where a customer and manufacturer have been sued in the same district "the concerns behind the customer suit exception—judicial economy and the

prevention of inconsistent outcomes—simply do not exist."); *Alloc, Inc., v. Unilin Decor N.V.*, No. 02-C-1266, 03-C-343, 04-C-121, 2005 WL 3448060, at *3 (E.D. Wis. Dec. 15, 2005) (where customer and supplier "are defending claims of infringement in the same consolidated suit in the same jurisdiction ... there is no issue of which jurisdiction should be granted priority and therefore the exception to the typical priority rule is inapposite"); *Naxon Telesign Corp. v. GTE Info. Sys.*, 89 F.R.D. 333, 339 (N.D. Ill. 1980); *Privasys, Inc. v. Visa Intern*, No. C 0-03257, 2007 WL 3461761, at *3-4 (N.D. Cal. Nov. 14, 2007) (collecting cases); *Lifelink Pharm., Inc. v. NDA Consulting, Inc.*, No. 5:07-CV-785, 2007 WL 2459879, at *3 (N.D. Ohio Aug. 24, 2007) ("granting a stay in such a situation would run counter to the goal of fostering judicial economy without enhancing the product source defendant's ability to litigate the issue of patent infringement"); *Precise Exercise Equip., Inc. v. Kmart Corp.*, No ED CV 00-312 RT (RCx), 2000 U.S. Dist. LEXIS 21500, at *6 (C.D. Cal. Oct. 24, 2000) ("the policy reasons behind the customer suit exception do not apply in this case because the manufacturer, the real party in interest, is able to defend against the infringement claim in this action."). Defendants cite to no authority that supports application of the rationale in this case. Accordingly, the Court should follow the reasoning of the many district courts above and deny Defendants' Motion.[2]

C. Litigation with only Estar will not resolve major issues of Defendants' infringement

1. Estar refuses to litigate and has two pending motions to dismiss

Without a doubt, the case against Estar cannot resolve major issues related to Defendants' infringement because Estar refuses to litigate RegenLab's claims on the merits. It is axiomatic that in order to stay a case at least one party must commit to litigate the patentee's claims.

[2] Moreover, Defendants lack standing to request this relief. The customer suit exception and its rationale are invoked by the manufacturer. Estar has chosen not to indemnify or otherwise defend Defendants, and Defendants' Motion can be denied on this basis alone.

Indeed, in every case cited by Defendants in their Motion manufacturers were litigating the substantive merits of the patentee's claims. (Dkt. 90.) Here, Estar has a pending Rule 12(b)(3) motion to dismiss, (Dkt. 42), a Rule 12(b)(6) motion on deck, (Dkt. 28), and has promised continued motion practice to avoid the substantive issues of this case, (Dkt. 73 at 1). Thus, Estar rejects any notion that it has a duty to litigate on behalf of Defendants. Instead, Estar's aim is to quickly exit this litigation and leave any U.S. defendants to fend for themselves while it continues to profit from its willful infringement.

At minimum, the Court should deny Defendants' request to sever and stay as premature pending the Court's resolution of Estar's pending and threatened motions.

2. Defendants commit separate and independent acts of infringement

A case only against Estar will not resolve major issues of infringement because Estar and Defendants commit separate and independent acts of infringement. When considering a stay a "primary question is whether the issues and parties are such that the disposition of one case would be dispositive of the other.'" *Tegic*, 458 F.3d at 1343 (parenthetically quoting *Katz v. Lear Siegler, Inc.*, 909 F.2d 1459, 1463 (Fed. Cir. 1990)). Method claims are at issue here, and even if Estar is found not liable for direct infringement or inducing Defendants' infringement, Defendants and their customers may still be liable for their own direct infringement and inducement. 35 U.S.C. § 271. For example, Estar and Defendants allege that they independently market and sell their own products, so an inducing activity by Defendants is not necessarily an inducing activity of Estar, and *vice versa*. Accordingly, litigation against Estar alone cannot resolve Defendants' liability and sever and stay would be inefficient, run contrary to the interests of judicial economy, and be prejudicial to RegenLab.

It is also worth noting that Defendants have not disputed the presence of any claimed feature in the accused products. Instead, Defendants only challenge *how* those products are used

and marketed. Meanwhile, Estar has not only challenged jurisdiction in the U.S. but has also submitted a sworn affidavit stating that "it has no customers in New York" and "has no control or input regarding where, how, or to whom the 'Eclipse PRP' product is sold by Eclipse." (Dkt. 44 ¶¶ 14, 30.) Accepting Estar's statements as true, litigation against Estar cannot resolve infringement in the U.S. because it apparently has no knowledge about how Eclipse's products are used or distributed. (Dkt. 44 ¶ 31.)

3. Estar and Defendants have knowledge of different products, distributors, and infringements[3]

A case only against Estar will also not resolve major issues of infringement because Estar and Defendants have different knowledge of infringements. For example, Eclipse distributes the Eclipse PRP product to Healeon (relabeled as Healeon PRP), (Dkt. 1 ¶ 64), to third-party Salient, http://www.prnewswire.com/news-releases/eclipse-offers-high-concentration-prp-tube-in-canada-300479412.html (last accessed Jul. 24, 2017), and potentially to others. Estar, meanwhile, maintains its only customer is Eclipse, and refuses to even acknowledge other distributors or products (including the Healeon PRP product). (Dkt. 44 ¶¶ 14, 36.) Estar has also stated its business activities are separate from Eclipse's. (Dkt. 44 ¶ 31.) At the same time, Estar distributes additional accused products in the U.S. under the brand names Tropocells, Ex. 1, Mycells, Ex. 2, and potentially others. For some products it distributes them directly, Pezzillo Decl. ¶ 14, while for others it utilizes distributors, Pezzillo Decl. ¶ 15. Estar has also stated that "Eclipse does not participate in Estar's business." (Dkt. 44 ¶ 31.)

Estar and Defendants' attempts to conceal infringement by blaming each other and setting up convoluted distribution schemes confirm that they are all necessary to determine liability for infringement, and judicial economy requires their presence in the litigation.

[3] RegenLab is assessing whether to add parties and products and will seek leave from the Court as necessary.

D. There is no legal authority for sever and stay here and the cases cited by Defendants are inapposite

The cases cited by Defendants provide no support for their request for sever and stay. For example, the Court in *In re Nintendo* noted that "the issues of infringement and invalidity are common to Nintendo and the Retailer Defendants." *In re Nintendo*, 756 F.3d 1363, 1366 (Fed. Cir. 2014). The Court further found that, "[s]ince Nintendo's liability is predicate to recovery from any of the defendants, the case against Nintendo must proceed first, in any forum." *Id.* at 1666. Here, the issues of infringement are not common between Estar and Defendants to warrant a stay, *see infra*, and Estar's liability for its own infringement is not a predicate to Defendants'.[4]

In *Katz*, the Federal Circuit merely concluded that stay of a customer suit was "within the court's discretionary authority." *Katz*, 909 F.2d at 1464. In *ProBatter*, a non-binding decision from the Northern District of Iowa, the parties did not dispute that determinations of infringement and validity would advance prosecution or resolution of the customer suit. *ProBatter Sports, LLC v. Joyner Techs., Inc.*, 463 F.Supp.2d 949, 956 (N.D. Ia. 2006). The Court in *ProBatter* also acknowledged a stay is not required, but discretionary. *Id.* (parenthetically quoting *Katz*). In addition, the customer lawsuits at issue in *Katz* and *ProBatter* were in *different* districts than the suit with the manufacturer.[5]

In contrast, the Federal Circuit, in *Kahn*, described application of the customer suit exception "where the first suit is filed against a customer who is *simply a reseller* of the accused goods, while the second suit is a declaratory action brought by the manufacturer of the accused goods." *Kahn v. General Motors*, 889 F.2d 1078, 1081 (Fed. Cir. 1989) (emphasis added). The

[4] Notably, at least one district court determined that a customer and manufacturer's presence in the same suit negated application of the customer suit exception even after *In re Nintendo*. *See Carucel Investments, L.P. v. Novatel Wireless, Inc.*, Case No. 16-cv-118-H-KSC, 2016 WL 8738221, at *2 (S.D. Cal. May 13, 2016).
[5] Customers were sued in four different districts in *ProBatter*. *ProBatter*, 463 F.Supp.2d at 952-53.

Court further stated that "in those cases in which a customer suit exception has been held to favor the forum of the second-filed action, the second action would resolve *all* charges against the customers in the stayed suit, including liability for damages." *Id.* (emphasis added). Here, Defendants are not "simply resellers," and litigation with Estar will not resolve all charges against Defendants (*see infra*).

Moreover, the Court in *Kahn* found that a customer's agreement to be bound by a judgment against Estar is a "controlling distinction" from previous cases where the exception was applied. *Id.* at 1082. Indeed, the fact that Defendants have not agreed to be bound strongly favors denial of their Motion. *Carucel Investments, L.P. v. Novatel Wireless, Inc.*, No. 16-cv-118-H-KSC, 2016 WL 8738221, n. 2 (S.D. Cal. May 13, 2016); *Spread*, 657 F.3d at 1358 (discussing *Kahn*); *Tegic*, 458 F.3d at 1343 (indicating whether litigate is "bound" is one of three factors for determining sever and stay); *Rates Tech., Inc. v. New York Telephone Co.*, No. 94 Civ. 9297 (DC), 1995 WL 438954, at *2 (S.D.N.Y. July 25, 1995); *Privasys, Inc. v. Visa Intern*, No. C 07-03257, 2007 WL 3461761, at *3 (N.D. Cal. Nov. 14, 2007).

E. RegenLab will be harmed by a sever and a stay

Defendants "must make out a clear case of hardship or inequity . . . if there is even a fair possibility that [a] stay … will work to damage" RegenLab. *Landis v. North Am. Co.*, 299 U.S. 248, 255 (1936); *accord U.S. v. Banco Cafetero Intern.*, 107 F.R.D. 361, 366 (S.D.N.Y. 1985). Defendants have not established any clear hardship or inequity. However, RegenLab can easily show a "fair possibility" that it will be damaged by sever and stay. If sever and stay is granted, Defendants will have no incentive to mitigate infringement and will continue to compete unfairly for RegenLab's customers without consequences. Pezzillo Decl. ¶ 17. Unfair competition includes not only the willful violation of RegenLab's patent rights, but the improper promotion of Defendants' products (evidenced by FDA enforcement). Defendants' activities have a

compounding effect on RegenLab because they induce their customers to both directly infringe and induce still others to infringe. The resulting erosion of the market and continued deluge of inferior products irreparably harms RegenLab through lost sales and profits. Pezzillo Decl. ¶ 16. In addition, sever and stay will harm RegenLab through duplicative proceedings as it will then need to pursue Defendants separately for their liability, even though they infringe using the same products (albeit relabeled). Pezzillo Decl. ¶ 17.

III. THE COURT SHOULD DENY DEFENDANTS' REQUEST TO ENJOIN PROSECUTION OF THE SECOND SUIT AND FUTURE SUITS[6]

Defendants seek to enjoin RegenLab from prosecuting its case against their customers, *RegenLab USA LLC v. Raj Kanodia, M.D. et al.*, No. 1:17-CV-03845-ALC ("the Second suit"), as well as any new lawsuits against customers. (Dkt. 90 at 7.) A preliminary injunction is a "drastic and extraordinary remedy," which requires a "moving party [to] demonstrate a reasonable likelihood of success on the merits, irreparable harm in the absence of a preliminary injunction, a balance of hardships tipping in its favor, and the injunction's favorable impact on the public interest." *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry.*, 357 F.3d 1319, 1324-25 (Fed. Cir. 2004); *cf. Oneida Nation of New York v. Cuomo*, 645 F.3d 154, 164 (2nd Cir. 2011).[7] The motion fails if either of the first two factors are not met. *Novo Nordisk A/S, v. Becton Dickinson and Co.*, 997 F.Supp 459, 465 (S.D.N.Y. 1998). Here, Defendants have failed to show entitlement to such a "drastic and extraordinary remedy" at least because they have failed to

[6] Pursuant to Federal Rule of Procedure 65, a bond is required if the Court grants any injunction. Fed. R. Civ. P. 65. In fact, Defendants cite cases that attest to the importance of a bond. For example, the court in *Johnson* found that an injunction was only appropriate if the petitioner for stay "is able to demonstrate its financial ability to pay any award which might be entered against it." *Johnson Elec. N. Am., Inc. v. Mabuchi Motor Am. Corp*., 1986 WL 5385, at *2 (S.D.N.Y. May 2, 1986).

[7] The Federal Circuit reviews a grant or denial of a preliminary injunction using the law of the regional circuit, but "has itself built a body of precedent applying [general preliminary injunction considerations] to a large number of factually variant patent cases, and [] give[s] dominant effect to Federal Circuit precedent insofar as it reflects considerations specific to patent issues." *Judkins v. HT Window Fashion Corp.*, 529 F.3d 1334, 1338 (Fed. Cir. 2008).

establish any specific harm. Nor have they identified a likelihood of success on the merits. Accordingly, Defendants' request to enjoin RegenLab's prosecution of the Second suit and future suits should be denied.

A. Defendants have failed to meet the high burden for an injunction

1. Defendants have failed to identify any specific harm

Defendants had the opportunity to demonstrate any harm in their Motion, yet they have failed to provide a single specific instance of harm. Such a showing is a prerequisite to demonstrate entitlement to an injunction. *Novo Nordisk,* 997 F.Supp at 465. Indeed, Defendants' Motion is devoid of any verifiable harm. The Declaration of Thomas O'Brien only provides general, conclusory, and contrived statements, along with unsupported conclusions of law, none of which should be given evidentiary weight. *See, e.g., Pineda v. Masonry Const., Inc.*, 831 F. Supp. 2d 666, 681 (S.D.N.Y. 2011) ("The Second Circuit has explained that a court may . . . strike portions of an affidavit that are not based on the affiant's personal knowledge, contain inadmissible hearsay or make generalized and conclusory statements.") (quotations omitted).

At minimum, RegenLab should be afforded a deposition of Mr. O'Brien so it can examine how he arrived at the conclusions contained in his declaration. For example, RegenLab is entitled to explore: how "Eclipse's reputation, goodwill, and standing within the aesthetic medical community has been severely damaged" and how "the reputation and good will associated with the Eclipse PRP product has been severely damaged" (Dkt. 90-9 ¶ 13); the content of the allegedly "numerous communications [Eclipse received] from concerned parties" (Dkt. 90-9 ¶ 14); what alleged "sales from customers that Eclipse was not able to complete" (Dkt. 90-9 ¶ 15); what alleged "communications from current and prospective customers [Eclipse received] that RegenLab representatives have been purposefully delivering and

promoting the press release" (Dkt. 90-9 ¶ 16)[8]; how Mr. O'Brien concludes "that the physicians using platelet concentrate created with Eclipse PRP product do not use it in combination with a cell extract," (Dkt. 90-9 ¶ 22), when "Eclipse Aesthetics, LLC asserts no control over the use of its Eclipse PRP product once it is in the hands of the medical professionals," (Dkt. 90-9 ¶ 24); and how Mr. O'Brien has firsthand knowledge of uses of the Eclipse PRP product by third-parties such that he can offer evidence on their behalf (Dkt. 90-9 ¶¶ 25-27). Granting any injunction before RegenLab has the opportunity to identify the factual bases for the conclusions would be premature and unfair.

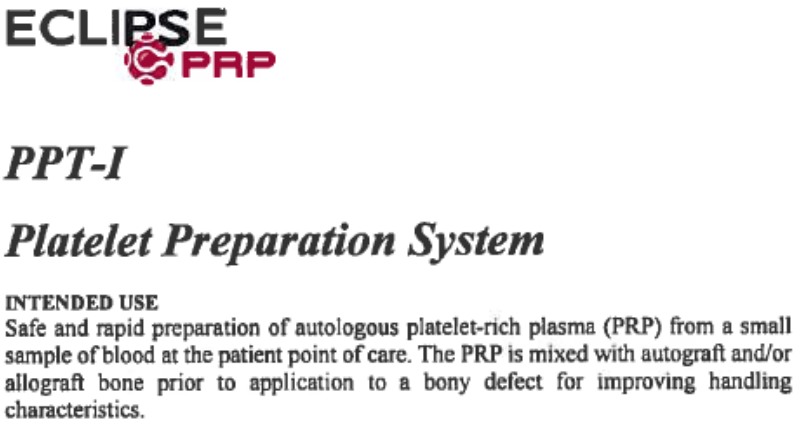
2. Defendants have failed to show a likelihood of success on the merits and have no standing to raise defenses on behalf of third-parties

As appreciated by the Court during the June 29 hearing, Defendants have an issue of standing because they cannot substantively litigate the merits of another suit. Defendants have failed to cite any authority that permits this and the law is clear that Defendants cannot raise defenses of third-parties. *See, e.g., Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (a party "cannot rest his claim to relief on the legal rights or interests of third parties"). Their proper course is to intervene or otherwise appear in the Second suit. *See* Fed. R. Civ. P. 24. Defendants nevertheless attempt to raise defenses on behalf of third-parties, none of which have even answered in the Second suit. In so doing Defendants seek to improperly elicit RegenLab's positions on issues more suitable for summary judgment. RegenLab briefly responds below.

Defendants' allegation that RegenLab brought the Second suit in bad faith is without merit. The only non-infringement defense raised by Defendants is that their customers allegedly

[8] The only documentary support provided by Defendants was an anonymous blog post in a "secret" Facebook group referred to in Exhibit 3 to Mr. O'Brien's declaration. RegenLab was unable to locate this Facebook group, much less identify the author. Pezzillo Decl. ¶ 8.

do not perform a step of mixing.[9] First, Defendants state they have no knowledge or control over how the Eclipse PRP product is used. (Dkt. 90-9 ¶ 24.) Second, they promote this very step. http://eclipseaesthetics.com/eclipse-prp-features-benefits/eclipse-prp-precautions-cautions-possible-side-effects/ ("The PRP is mixed with autograft and/or allograft bone prior to application") (last accessed Jul. 24, 2017). In fact, the Eclipse PRP product is packaged with instructions that instruct this very step:

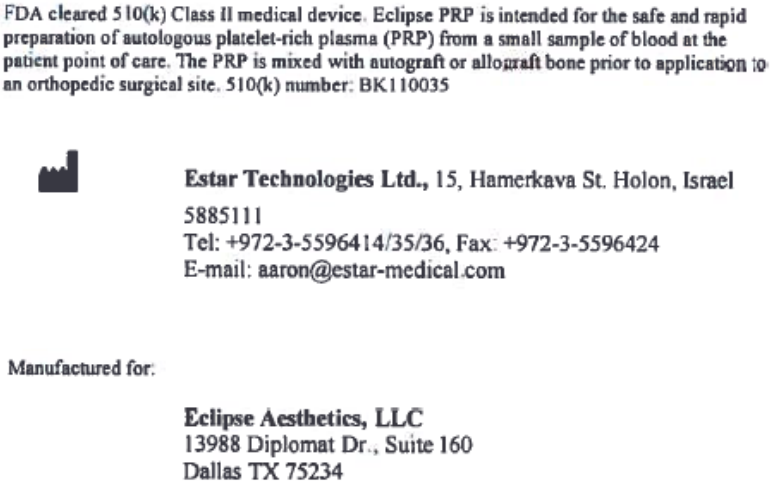

ECLIPSE PRP

PPT-I

Platelet Preparation System

INTENDED USE
Safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of blood at the patient point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Ex. 3 at 1.


FDA cleared 510(k) Class II medical device. Eclipse PRP is intended for the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of blood at the patient point of care. The PRP is mixed with autograft or allograft bone prior to application to an orthopedic surgical site. 510(k) number: BK110035

Estar Technologies Ltd., 15, Hamerkava St. Holon, Israel
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Tel: +972-3-5596414/35/36, Fax: +972-3-5596424
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Manufactured for:

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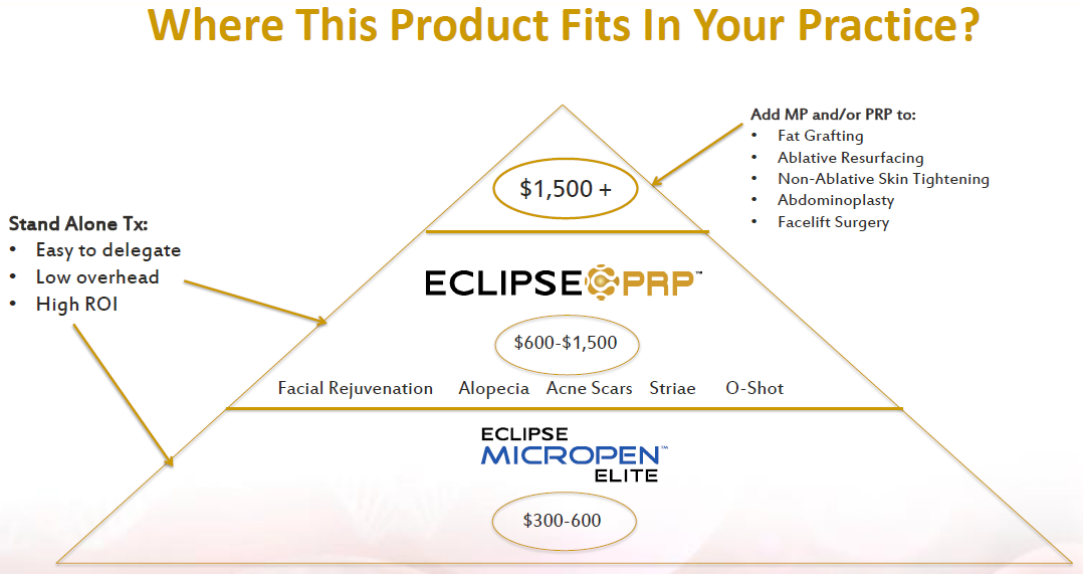
[9] RegenLab notes that there are non-infringing alternatives in the market. Pezzillo Decl. ¶ 12. However, Estar and Defendants have instead willfully infringed RegenLab's patent rights by copying RegenLab's products. (Dkt. 1 at ¶¶ 77, 92.)

Ex. 3 at 2. These instructions are in accordance with the approved uses for the accused products that result in infringement of RegenLab's patent rights. (Dkt. 1 ¶¶ 84, 88.) Accordingly, there is at least *per se* inducement by any party that markets and sells the Eclipse PRP product.

In addition, Eclipse PRP customers advertise the mixing of platelet concentrate with a number of different compositions. *See* Pezzillo Decl. ¶¶ 3, 5. This is done specifically in relation to Eclipse's products:



Ex. 4 at 58. In another example, an Eclipse customer advertises the combination of platelet concentrate with stem cells and growth factors to treat acne and enhance skin rejuvenation. *See* https://cosmediclaserclinic.com/eclipse-prp/ (last accessed Jul. 22, 2017). *See also* http://cosmeticsurgeryandwellness.com/blog/page/2/ ("'stand-alone treatments are more often than ever becoming somewhat obsolete,' says Tom O'Brien, CEO of Eclipse Aesthetics…'These treatments are being replaced with combination therapies"; also discussing combination of fat grafting and platelet concentrate) (last accessed Jul. 24, 2017); http://www.prweb.com/releases/miamiprpsymposium/drrossclevensmiami/prweb9521010.htm (Eclipse guest speaker to discuss "Autologous fat grafting with PRP") (last accessed Jul. 24,

2017). The FDA has even acknowledged Eclipse's promotion of "combination procedures" including platelet concentrate and "fillers." https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm480331.htm (last accessed Jul. 24, 2017). In addition, Estar promotes "combining PRP with a range of clinically & commercially valuable biologics, such as hyaluronic acid, collagen, bone substitutes." http://estar-medical.com/us/pipeline/ (last accessed Jul. 24, 2017). Accordingly, it is entirely disingenuous for Mr. O'Brien to state that platelet concentrate is not mixed with cell extracts based on "industry norms." (Dkt. 90-9 ¶ 22.)

Still further, Defendants acknowledge the use of micro-needling procedures in their Motion, (Dkt. 90 at 7), and micro-needling is promoted in combination with platelet concentrate and other topical treatments. Pezzillo Decl. ¶ 4. Such treatments include the mixing of collagen, fat cells, and stem cells, in violation of RegenLab's patent rights. Pezzillo Decl. ¶ 4; *see also* http://aestheticchannel.modernmedicine.com/cosmetic-surgery-times/news/latest-prp?page=0%2C2 ("He mixes PRP with fat transfer to increased (sic) fat cell survival during transfer. Using the MicroPen [Eclipse Aesthetics] microneedling device, Dr. Manolakakis says he injects platelets into the epidermis.") (last accessed Jul. 24, 2017); http://www.belleamerejuvenation.com/single-post/2016/02/25/The-latest-on-PRP (last accessed Jul. 24, 2017). Numerous Eclipse customers promote the combination of platelet concentrate and cell extracts in videos posted online. https://www.facebook.com/160783127344687/videos/1050203368402654/ ("PRP is great to use on the skin topically after laser treatments and I mix it with fat every time I do a fat transfer" and video showing same) (last accessed Jul. 24, 2017); https://www.youtube.com/watch?v=hWU6INBc4B0&index=6&list=PLDu_uNoV_IUg6uwkr18

RWCk7KLZYBz5h0 ("The fat is first harvested, mixed with PRP, and then reinjected into the face to give the patient more fullness" and video showing same) (last accessed Jul. 24, 2017); https://www.youtube.com/watch?v=zJZWoYzSrIM (video with mixing) (last accessed Jul. 24, 2017).

Defendants then improperly attempt to raise the so-called "doctor immunity statute" on behalf of third parties. 35 U.S.C. § 287(c). However, they misstate the law. In truth, it is a narrow law with a broad exception:

> This subsection **does not apply to the activities of any person**, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), **who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine**, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), where such activities are:
>
> (A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and
>
> (B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

35 U.S.C. § 287(c)(3) (emphases added). As alleged by RegenLab, the named defendants in the Second suit are directly engaged in the commercial sale and distribution of the Eclipse PRP product. This includes the use of promotional videos and other advertising, one even offering the product on its website for an "UNBEATABLE PRICE!"[10] (*RegenLab USA LLC v. Raj Kanodia, M.D. et al.*, No. 1:17-CV-03845-ALC, Dkt. 1 ¶ 47.) A nearly identical scenario was presented in *Viveve, Inc., Inc. v. Thermigen, LLC et al.*, No. 2:16-CV-1189-JRG, 2017 WL 1425604 (E.D. Tex. April 20, 2017) (Judge Gilstrap). In that case, the court found a doctor's promotion of a procedure was a commercial activity that rendered the doctor immunity statute inapplicable. *Id.*

[10] This commercial promotion is similar to that by Healeon, which Eclipse has acknowledged is one of its customers, (Dkt. 90 at 1.) However, Defendants have never raised a doctor immunity defense on behalf of Healeon.

Just like in that case, the doctor immunity statute does not apply to the defendants in the Second suit.[11]

Finally, Defendants fail to even address the two remaining prongs for showing entitlement to injunctive relief, the balance of hardships and the public interest. *Nat'l Steel Car*, 357 F.3d at 1324-25; *see also CollaGenex Pharms., Inc. v. IVAX Corp.*, 375 F. Supp. 2d 120, 123 (E.D.N.Y. 2005) (stating that upon "failure to make a clear showing of any one of the four factors, a trial court may deny the motion."). The balance of hardships easily tips in RegenLab's favor as the non-movant who has had its patent rights willfully infringed by a former business partner. The public interest also is in favor of maintaining patent rights and protecting the public from unsafe products (see *infra* for discussion of Eclipse's FDA violations).

IV. THE COURT SHOULD DENY DEFENDANTS' REQUEST TO ENJOIN REGENLAB'S ACTIVITIES OUTSIDE THE LITIGATION

As discussed *supra*, a preliminary injunction is a "drastic and extraordinary" remedy that requires a showing of irreparable harm and a reasonable likelihood on the merits. Here, Defendants' request to enjoin RegenLab's activities outside this litigation fails for many of the same reasons discussed above. Again, Defendants have not shown any specific or verifiable harm from RegenLab's press release ("the Press Release") (or any other activity outside this litigation), and further fail to establish a likelihood of success on the merits.

A. Defendants have failed to meet the high burden for an injunction

1. Defendants have failed to identify any specific harm

As an initial matter, RegenLab has not sent any threatening letters, nor have Defendants identified any such letters. RegenLab sent three letters to defendants in the Second suit advising

[11] Defendants also state that RegenLab's patent "may be invalid," but this meek assertion is wholly insufficient to amount to a likelihood of success on the merits. 35 U.S.C. § 282.

them of the allegations. There is nothing improper about this and Defendants have not identified any case law supporting their position that such communications should be enjoined.

As discussed *supra*, RegenLab has more than demonstrated that the Second suit was brought in good faith. In addition, Defendants have not identified anything inaccurate in the Press Release. Defendants appear to take issue with the term "infringing product," but this is a term they used (accused infringing product) in their first filing in this case. (Dkt. 29.) Defendants have identified no legal authority in support of their position. Moreover, as discussed *supra*, the product is packaged with instructions that induce infringement, which creates *per se* inducement through its sale.

Finally, Defendants have failed to identify any customer that received a copy of the press release, much less was persuaded to change its behavior after receiving the press release. RegenLab is unaware of any employee who gave a copy of the press release to a customer. Pezzillo Decl. ¶ 7.

2. Defendants have failed to show a likelihood of success on the merits, agree that RegenLab has a right to report on the litigation, and have issued similar press releases in the past.

Defendants have failed to show a likelihood of success on the merits. Instead, Defendants admit that RegenLab has a right to report facts of good-faith claims. (Dkt. 90 at 7 ("Defendants will acknowledge that a patent owners (sic) ordinarily has the right to make others aware of their patent rights . . . .").) Any allegations of harm by Defendants are disingenuous because they have issued similar press releases in the past. *See, e.g.* Ex. 5 ("RegenLab USA knowingly sending a false, fraudulent, and deceptive Promotional (sic) E-mail that was intentionally designed to disparage Eclipse and Eclipse PRP™ while damaging its standing within the medical care community"). Indeed, use of press releases is a common business practice and Defendants provide no legal support for enjoining their use.

Again, Defendants fail to even address the two remaining prongs for showing entitlement to injunctive relief, the balance of hardships and the public interest. *Nat'l Steel Car*, 357 F.3d at 1324-25; *see also CollaGenex*, 375 F. Supp. 2d at 123. Those fall in favor of RegenLab for the reasons discussed above.

3. Any harm to Defendants has been self-inflicted

In reality, Defendants' allegations of harm have nothing to do with RegenLab. Instead, it is caused by Defendants' egregious business practices, including the theft of RegenLab's patented technology and repeated FDA regulatory violations. Defendants' willful infringement is well documented in the Complaint. (Dkt. 1 ¶¶ 84-86, 91.) In addition, the FDA has issued multiple cease and desist letters to Eclipse. (Dkt. 1 ¶¶ 31, 60, 61.) The FDA has repeatedly identified concerns with Eclipse's activities that raise serious safety issues. These are public knowledge and a major reason why customers might not want to risk patient safety buying products from Defendants.

In addition, the Eclipse PRP product is simply an inferior product in the marketplace. Although Estar and Defendants have done their best to copy RegenLab's technology, (Dkt. 1 at ¶¶ 77, 92), the accused products have defects and RegenLab remains the market innovator, as evidenced by its patent portfolio. For example, it is known that the Eclipse PRP product suffers from "bleed-through" between the platelet concentrate and red blood cells. Pezzillo Decl. ¶ 11. This adversely impacts effectiveness of any procedure using the accused products. Pezzillo Decl. ¶ 11.

Still further, Eclipse has a poor reputation in the industry. This is one reason why many former Eclipse salespeople have tried to obtain employment with RegenLab. Pezzillo Decl. ¶ 10. These salespeople have complained that Eclipse never properly trained them on how to use the Eclipse PRP product. Pezzillo Decl. ¶ 10. This has likely lead to a high-turnover rate and poor

service for Eclipse's customers.

In short, there are numerous reasons why Defendants' reputations and the reputations of the accused products suffer in the industry that have nothing to do with RegenLab.

V. DEFENDANTS' MOTION IS AN UNNECESSARY DELAY TACTIC AND IS FRUSTRATING POTENTIAL RESOLUTION

It has become evident that neither Estar nor Defendants have an interest in litigating the substantive issues related to their infringement. Instead, they continue to utilize abusive, serial motion practice to delay resolution of RegenLab's claims. Now, Defendants' Motion is frustrating resolution with third-parties. Defendants never sought to meet and confer with RegenLab before proceeding with their Motion. Indeed, it is clear that they want to hijack proceedings in the Second suit for their own self-interest and at the expense of the customers they purport to be protecting.

RegenLab has no interest in pursuing non-infringers. If the defendants in the Second suit legitimately believe their activities are not infringing, the proper course is for them to contact RegenLab in that case.[12] Instead, Defendants have inserted themselves so that RegenLab cannot discuss potential resolution with those defendants. The reason Defendants have done so is clear: they are willful infringers who have thrown their customers under the bus by inducing them to infringe RegenLab's patent rights. They are now trying to save themselves from having to indemnify their customers by preventing those customers from resolving their case.[13]

[12] The first evidence RegenLab was provided to substantiate any non-infringement claims was with Defendants' Motion. Pezzillo Decl. ¶ 13.

[13] Counsel for Defendants likely have a conflict of interest because their clients have differing interests. NY R. Prof. Con. 1.7. Eclipse is trying to insulate itself from its customer's infringement by stating "Eclipse Aesthetics, LLC asserts no control over the use of its Eclipse PRP product once it is in the hands of the medical professionals." (Dkt. 90-9 ¶ 24.) In addition, RegenLab's damages may be apportioned among Estar, Defendants, and their customers. *See, e.g., Syntex (U.S.A.) Inc v. Paragon Optical Inc.*, 7 U.S.P.Q. 1001, 1987 WL 124333 (D. Ariz. 1987) *aff'd* 856 F.2d 202 (Fed. Cir. 1988). Defendants will likely argue their customers bear a majority share since they have the highest profit margin at the end of the distribution chain.

RegenLab believes at present that litigation with Estar and both Defendants can provide RegenLab its full relief. Accordingly, in an effort to resolve this dispute and advance the case RegenLab is willing to voluntarily stay the Second suit if Estar and both Defendants agree to litigate the substantive issues in this case. The only reason they would not accept such an offer is because they intend to shift liability to their customers.

Respectfully Submitted,

Date: July 24, 2017

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CERTIFICATE OF SERVICE

This is to certify that on this 24th day of July, 2017, a true and correct copy of the foregoing Opposition To Defendants' Motion For Preliminary Injunction and Stay, Declaration of John Pezzillo and Exhibits 1 – 5, were filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the court's CM/ECF System.

July 24, 2017
Date

/s/ Joan M. Burnett
Joan M. Burnett